

This is an untilled letter from Moreville MD TRECEIVED

Food and Drug Administration

APR 1 0 1997

LAW DEPARTMENT

Monica Krieger, Ph.D. CellPro, incorporated 22215 26th Avenue SE Bothell, Washington 98021 Rick Suggested everyone have a copy so we waderstand the level

Dear Dr. Krieger:

We are in receipt of a holiday greeting card that was disseminated by your company during the month of December, 1996. A copy is enclosed. Appearing on the back cover of the card is information about the artist which contains facts and efficacy claims related to a new indication for use of your CEPRATE® SC Stem Cell Concentration System for which a supplemental application has not been approved. As described in the conditions for approval of this device, no advertisement or other descriptive printed material issued by you or a distributor shall recommend or imply that the device may be utilized for uses that are not included in the FDA approved labeling.

The CEPRATE® SC Stem Cell Concentration System, manufactured by CellPro, Inc., is considered to be a device within the meaning of section 201(h) of the Federal Food Drug and Cosmetic Act (the Act). This device was approved for sale and distribution as a restricted device under the Premarket Approval (PMA) process described in section 515(d)(1)(B)(ii) of the Act for the following indication [flaterence PMA Number 8P940001]:

"...tor the processing of autologous bone marrow to obtain a CD34+ cell enriched population which is intended for hematopoietic support after mycloablative chemotherapy."

The specific areas of concern related to the promotion of this device are noted below.

 In your "about the artist" profile, a brief discussion regarding the use of the CEPRATE system in allogeneic stem cell transplants appears in the second paragraph.

The evaluation of stem cell transplants from allogeneic donors (e.g. use of stem cells from parents who are half-matched at tissue type antigens) is still experimental. Thus far, the Center for Biologics Evaluation and Research (CBER) has not received data from you that would render conclusive evidence to base your claim for use of the device in allogeneic transplants thereby expanding the donor pool and providing many more children with curative treatment of high risk leukenia. The new indication for use of this device described above may not be promoted until a PMA Supplement has been submitted and approved.

b. In the third paragraph of the "about the artist" profile, the following claim is made: "Selecting stem cells reduces the chances of severe graft-versus-host disease that would otherwise occur if a child were to receive a half-matched bone marrow transplant from a parent"

CBER has not received a supplement to your PMA providing the clinical data that would provide the evidence needed to support this claim. In the absence of this information, one cannot conclude that CEPRATE®-selected (T- cell depleted) allogeneic transplants will prevent graft-versus-host disease or otherwise confer a benefit to the patient.

The above mentioned misrepresentations or like misrepresentations about the CellPro CEPRATE® device misbrand your product under Section 502(o) in that you have falled to comply with Section 515 of the Act. Section 515 of the Act requires that you file a PMA Supplement in accordance with the provisions described in 21 CFR Part 814.39. This regulation requires that an applicant submit a PMA Supplement before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. We have determined the aforementioned claims regarding the CEPRATE® system affect both the safety and

Page 3 Dr. Krieger

efficacy of this device and, therefore, require the submission of a supplement that would provide the definitive evidence to support such claims.

In addition, as a restricted device, you are further misbranding your device under Section 502(q)(1) of the Act, by including uses and claims in your advertising for this device that are regarded to be false and misleading.

It is your responsibility to ensure that the violations noted in this letter that may appear in other advertising or promotional materials are also corrected. You should take prompt action to correct the violations noted and assure compliance with the applicable regulations.

Please respond to this staff, in writing, within 15 days of the receipt of this letter. Your response should include the steps you plan on taking to remedy the above noted observations. Please send your response to the attention of:

Ms. Toni M. Stifano

Center for Biologics Evaluation and Research

- Advertising and Promotional Labeling Staff, HFM-202

1401 Rockville Pike

Rockville, MD 20852-1448

Sincerety yours.

William V. Purvis

Director, Advertising and Promotional

Labeling Staff

Center for Biologics Evaluation and Research

Enclosure

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numerous bone marrow texts and spoudle green the like blandsream intertwine and term proyou and dealers and drop treatments. They was was agenous the file and all her recatourers of a complex stooms post a few months but and required noor ynter minully responded to the chemidle cape of religions levers and has bland counts. Atthough his AM week at the temperal and had problem, with ages and only a secundary of the second of the second on t moderate and moderate to discovered to H Har when he was set setts old. Thousas was dup about all the disperalicality are several disperhis circle bracketis, in September 1996, and discount Human Carren and haladay grows arrive or helitate!

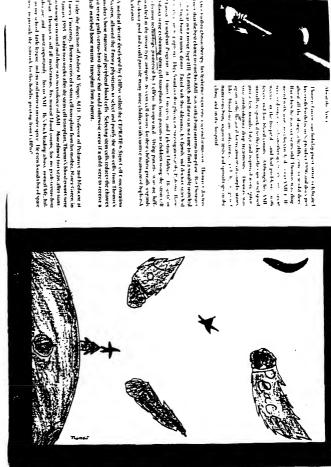
the should pend and could provide many above children with cutative reconsented high-risk material at the tresse type antiques, as your cell donner for their children preath expands times that the best chance to cure his AMI was with a bone institute transplant. But Dissusses . In most technicalings promeered by fellifur the orporated. Using parents war are halfvalues were evaluating stem cell transplants from parents to children using the stem cell Speece Transplant Program at Funes University and Lighten Children. The getal of er einer der er ergebenste blev fonndere den glasse en masstigationsende, Bekente Benedict Charles the mather apy first backerner were noted a second remassion. The mass of the base ... the distance marries donor. Faced with this difference, his family and idea has systemal the reason of a record type (11). A finatch and there was not time to find a sociable matched

mother's home marrow and peripheral blookleells. Selecting stem cells reduces the chances System, allowed the Emory physicians to select and punify the stem cells from Thomas's A method device descriped by CellPin collectibe CEPRATE's Stem Cell Concentration half matched bone matrox transplant from a parent. ist tevere graft-versus-host disease that would inherwise ration if a child were to receive a

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dealer, and anost enportantly have AMI. This backleading above owned life, but plant. They are as off all medications, has instead blood counts, has no graditiversus-host removing terminal and there has meet where id AMI. Now almost too vears after trans-Limites 1995. Within two weeks after the stem cell transplant. Thomas's blood entires were I more I inversity. Thomas received a demicell maniplant from his mother. Nancy Green, in Under the direction of Andrew N. Yenger, M.D. Professor of Pediatrics and Medicine at

ness in provide the astwork for this holiday greeting from tellProf



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